**IN THE UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF OHIO**
**EASTERN DIVISION**

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| **IN RE: E. I. DU PONT DE NEMOURS AND COMPANY C-8 PERSONAL INJURY LITIGATION** | **CASE NO. 2-13-MD-2433**<br><br>**CHIEF JUDGE EDMUND A. SARGUS, JR.**<br><br>**CHIEF MAGISTRATE JUDGE ELIZABETH P. DEAVERS** |

**This document relates to:**
*Swartz v. E. I. du Pont de Nemours and Company, Case No. 2:18-cv-0136*

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**PLAINTIFFS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF DEFENSE EXPERT DR. SAMUEL COHEN**

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Plaintiffs, by and through undersigned Counsel, hereby submits this motion and supporting memorandum requesting that this Court exclude the opinions and testimony of defense expert Dr. Samuel Cohen. For the reasons set forth in the attached Memorandum of Law in Support of Plaintiffs' Motion to Exclude Opinions and Testimony of Defense Expert Dr. Samuel Cohen, Dispositive Motions Orders Nos. 1 [ECF No. 1679], 1-A [ECF No. 3972], and Evidentiary Motions Order Nos. 1 [ECF No. 4079], 1-A [ECF No. 4226], and 5 [ECF No. 4532], where this Court previously excluded similar opinions and testimony, Plaintiffs respectfully requests that this Court grant said motion and any all other relief the Court deems just and proper.

Respectfully submitted,

*/s/ Jon C. Conlin*

Jon C. Conlin
CORY WATSON, P.C.
2131 Magnolia Ave., Suite 200
Birmingham, AL 35205
Telephone: 205-328-2200

Fax: 205-324-7896
Email: c8@corywatson.com

Elizabeth E. Chambers
Nina M. Towle
Brett Thompson
CORY WATSON, P.C.
2131 Magnolia Ave., Suite 200
Birmingham, AL 35205
Telephone: 205-328-2200
Fax: 205-324-7896
Email: c8@corywatson.com

***Counsel for Plaintiffs***

## SUMMARY OF POINTS AND AUTHORITIES

Pursuant to Local Rule 7.2(a)(1), Plaintiff submits the following summary of points and authorities cited:

**IN THE UNITED STATES DISTRICT COURT**
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**MEMORANDUM IN SUPPORT OF TRIAL PLAINTIFFS' MOTION FOR THE EXCLUSION OF OPINIONS AND TESTIMONY OF DEFENSE EXPERT WITNESS DR. SAMUEL COHEN RELATING TO GENERAL CAUSATION**

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Trial Plaintiffs Angela Swartz and Teddy Swartz ("Plaintiffs"), through Counsel, submit this Memorandum in Support of Plaintiffs' Motion for the Exclusion of Opinions and Testimony of Defense Expert Witness Dr. Samuel Cohen Relating to general causation.

## I. INTRODUCTION

Defendant E.I. du Pont de Nemours and Company's ("DuPont") expert, Dr. Samuel Cohen, proffers both irrelevant general causation opinions in violation of this Court's prior holdings[1] and methodologically unsound specific causation opinions. These opinions fail to meet the strict standards of Federal Rule 702, *Daubert v. Merrell Dow Pharm., Inc.*, and its progeny. As set forth more specifically below, Dr. Cohen's opinions should be excluded entirely.

[1] Plaintiff references, adopts, and incorporates this Court's prior holdings in Dispositive Motions Orders Nos. 1 [ECF No. 1679], 1-A [ECF No. 3972], and Evidentiary Motions Order Nos. 1 [ECF No. 4079], 1-A [ECF No. 4226], and 5 [ECF No. 4532].

Under Federal Rule of Evidence 702 and *Daubert*, an expert opinion is not admissible unless it is ***relevant*** to the facts of a specific case. *See Daubert v. Merrell Dow Pharm. Inc.*, 509 U.S. 579, 590-92 (1993) (because Federal Rule of Evidence 702 "requires that the evidence or testimony 'assist the trier of fact to understand the evidence,'" expert testimony "which does not relate to any issue in the case is not relevant and *ergo*, nonhelpful"). Because general causation has been determined by this Court to not be a "fact in issue" in light of DuPont's contractual agreement in the *Leach* Class Action Settlement Agreement (the "Contract"), Dr. Cohen's opinions regarding class members low dose and exposure to C8 resulting in only a 10% increased risk of cancer do not fit the issues presented and would not be helpful to the trier of fact.

Moreover, under Sixth Circuit law, the appropriate methodology when proffering a case-specific causation opinion is a proper differential diagnosis. Dr. Cohen failed to conduct a proper differential diagnosis by refusing to "rule in" and "rule out" C8 as a cause of Plaintiff's injuries using the required definition provided by the Probable Link Report. Dr. Cohen's repeated insistence that Plaintiff's exposure was "low" and not a "significant risk factor" because of where she fell within the tiers of class members demonstrates that C8 was never properly "ruled in" or "ruled out" as defined by the Probable Link Evaluation assaulting this Court's prior holdings and rendering his specific causation opinions unreliable.

Finally, even though an individual might have expertise in a specific area of medicine or science, that alone does not mean that he can provide expert opinions on all tangentially related issues. It is undisputed that a proposed expert's opinion is only admissible, at the discretion of the trial court in its role as gatekeeper, if the opinion satisfies three requirements. First, the witness must be qualified by "knowledge, skill, experience, training, or education." FED. R. EVID. 702.

Second, the testimony must be relevant, meaning that it "will assist the trier of fact to understand the evidence or to determine a fact in issue." *Id.* Third, the testimony must be reliable. *Id.*

Rule 702 guides the trial court by providing general standards to assess reliability: whether the testimony is based upon "sufficient facts or data," whether the testimony is the "product of reliable principles and methods," and whether the expert "has applied the principles and methods reliably to the facts of the case." *Id.* In addition, *Daubert* provided a non-exclusive checklist for trial courts to consult in evaluating the reliability of expert testimony and whether an expert has the requisite qualifications to provide a specific opinion. These factors include: "testing, peer review, publication, error rates, the existence and maintenance of standards controlling the technique's operation, and general acceptance in the relevant scientific community." *United States v. Langan*, 263 F.3d 613, 621 (6th Cir. 2001) (citing *Daubert*, 509 U.S. at 593–94).

In sum, as set forth herein, in addition to being improperly based on a foundational attack on general causation, certain of Dr. Cohen's opinions should be excluded, because they are irrelevant, unreliable, fail to meet the requirements set forth in *Daubert* and Rule 702, and violate the terms of the *Leach* Contract for the same reasoning previously addressed and explained by this Court.[2]

## II. FACTUAL BACKGROUND

The history of the first phase of this litigation, leading up to final approval of the Contract has been summarized in connection with prior motions and is incorporated by reference herein. In summary, the Leach Court approved the Contract between the plaintiffs and DuPont on February 28, 2005. Under the terms of the Contract, DuPont and the plaintiffs jointly selected three independent epidemiologists (the "Science Panel") to study human disease among the Leach Class

[2] Plaintiff references, adopts, and incorporates this Court's prior holdings in Dispositive Motions Orders Nos. 1 [ECF No. 1679], 1-A [ECF No. 3972], and Evidentiary Motions Order Nos. 1 [ECF No. 4079], 1-A [ECF No. 4226], and 5 [ECF No. 4532].

Members to determine whether the approximately 80,000 individual Leach Class Members would be allowed to pursue individual claims against DuPont based on any of the human diseases they believed had been caused by exposure to C-8. (Contract § 12.2.2; DMO 1 at 2 [ECF No. 1679]; DMO 12 at 2-8 [ECF No. 4306]).

Under the terms of the Contract, the parties agreed that the Science Panel would release their results in the form of either a "Probable Link Finding" or a "No Probable Link Finding" for each of the human diseases studied by the Science Panel. (Contract § 12.2.3; DMO 1 at 3; DMO 12 at 2-8). In 2011 and 2012, the Science Panel delivered "Probable Link Findings" for the following human diseases: kidney cancer; testicular cancer; thyroid disease; ulcerative colitis; hypercholesterolemia; and pregnancy-induced hypertension and preeclampsia. (DMO 1 at 3). For those plaintiffs with human diseases for which the Science Panel delivered a "No Probable Link Finding," those plaintiffs "are forever barred from bringing personal injury or wrongful death claims against DuPont based on injury or death allegedly resulting from those human diseases." (*Id*. at 5). Only those plaintiffs with human diseases for which the Science Panel delivered a "Probable Link Finding" are now allowed to pursue individual personal injury or wrongful death claims, thousands of which are now pending in the multidistrict litigation before this Court. (*Id.*; DMO 12 at 2-8).

On December 17, 2014, this Court entered Dispositive Motions Order No. 1 regarding Class Membership and Causation. (*See generally* DMO No. 1). In that Order, the Court ruled that both Plaintiffs and DuPont agree, and the Court finds, that the parties are all bound by the Contract. (*Id.* at 6). As to the issue of class membership, both Plaintiffs and DuPont agreed that "as part of the individual plaintiffs' cases, they must show that they are a class member and that they have one or more of the Linked Diseases." (*Id.* at 7). Pursuant to the Contract, in order to prove class

membership, a plaintiff must show that he or she, "for the period of at least one year," has "consumed drinking water containing .05 ppb or greater of C-8 attributable to releases from [DuPont's] Washington Works" plant from any of the "six specified Public Water Districts" or any of the Covered Private Sources" identified in the Contract. (*Id.* at 7; Contract § 2.1.1).

Although all parties agree they are bound by the Probable Link Findings, DuPont argued it is nonetheless permitted to "point[] out the nuances and the limitations of the Science Panel's findings," because the Science Panel's Probable Link Findings purportedly "include the reasoning and the clarifications on what they did find and, just as importantly, what they did not find." (DMO 1 at 8 (*citing* Mots. Hr'g. Tr. ("Tr.") at 24, 34 [ECF No. 1519]). In other words, DuPont argued that the "Probable Link Findings may not apply to a particular plaintiff, such as those plaintiffs who were in the lowest exposure groups." (*Id.* at 24). DuPont also argued that the Probable Link Findings "contain other limitations, including certain objective criteria such as male versus female, main versus prospective analysis, inclusion or exclusion of experience before onset of elevated exposure." (*Id.* at 8, n. 3 (citing Tr. at 26)).

In response, Plaintiffs pointed out that the Probable Link Findings apply to anyone who meets the definition of a class member who has one or more of the Linked Diseases, which means that any plaintiff who meets the definition of "Class Member," by definition under the parties' Contract, has a sufficient exposure to or "dose" of C-8 to cause the linked disease, whether they are in the highest or lowest "dose" group or any other subcategory or subgroup within the Class, resulting in "any issue about the C-8 dosage and whether it's sufficient to have caused this [Linked Disease being] off the table." (*Id.* at 8-9).

The Court agreed with Plaintiffs, rejecting DuPont's analysis as not being tenable under the Contract on the basis that "the unambiguous language of the Leach Settlement Agreement

unequivocally provides for application of the Probable Link Finding to any class member with the Linked Disease for which the finding was issued, and that for those individuals DuPont waived the right to challenge general causation." (*Id.*) Further, the Court pointed out that "[i]f the Science Panel issued a Probable Link Finding that it was "more likely than not that there is a link between exposure to C-8 and a particular Human Disease among Class Members," the Panel then issued a Probable Link Finding for that specific disease and DuPont waived its right to challenge whether "it is probable that exposure to C-8 is capable of causing" the Linked Disease, *i.e.*, general causation." (*Id.* at 9; Contract § 3.3). The Court ruled that DuPont cannot now prevent a class member from the benefit of the Probable Link Findings by "pointing out the 'limitations' in the objective criteria and/or protocols the Science Panel utilized to make its conclusions or by extrapolating from the Science Panel's analysis what the Panel 'did not find' in its Probable Link Finding." (DMO No. 1 at 9-10). The Court recognized that the Science Panel "'did not limit [its Findings] to only certain exposure groups or only people that were quartile one versus quartile two – they said the link existed among the entire group.'" (*Id.* at 10 (citing Tr. at 11)). The Court's rulings in this regard were clarified in DMO No. 1-A, expounded upon in connection with the Prior *Daubert* Motions in EMO No. 1, EMO No. 5, and in DMO No. 12.

## III. LEGAL ARGUMENT

### A. Legal Standard

Under Rule 702 of the Federal Rules of Evidence and *Daubert*, an expert opinion is not admissible unless it is ***relevant*** to the facts at issue in the case. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589-91 (1993) (emphasis added). In *Daubert*, the United States Supreme Court held that the Federal Rules of Evidence Rule 702 and 104(a) govern the admission of expert witness testimony and require that the trail judge "ensure that an and all scientific testimony or evidence admitted is not only relevant, but reliable. *Daubert*, 509 U.S. at

589. Because 702 "requires that the evidence or testimony 'assist the trier of fact to understand the evidence," expert testimony "which does not relate to any issue in the case is not relevant and ergo, nonhelpful." *Daubert*, 509 U.S. at 590. "In other words, there must be a 'fit' between the proposed testimony and the question(s) presented by the case at bar." *Daubert*, 590 U.S. at 591.

The burden is on the part proffering the expert report to demonstrate by a preponderance of proof that the opinions of their experts are admissible. *See, e.g., Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d at 244; 251 (6th Cir. 2001).

**B. Dr. Cohen Offers Irrelevant and Inadmissible General Causation Opinions in his Expert Report.**

Through the proposed expert report and opinions of Dr. Samuel Cohen, Defendant AGAIN makes it clear that it fully intends to dispute and challenge general causation in this litigation on at least two levels: (1) that the Probable Link Evaluation only increased class member's risk of getting cancer by 10%, instead of the defined "more likely than not" and (2) that class members with low C8 blood levels and water exposure had a lesser chance of getting cancer than other class members with higher C8 blood levels and water exposure. Defendant attempts to disguise this attack on general causation by directing it specifically at Plaintiff Angela Swartz but either opinion is still explicitly challenging general causation which is expressly prohibited under the parties' binding contract and this Court's prior Orders. Therefore, Dr. Cohen's report and opinions should AGAIN be precluded in this litigation on the same rationale as previously applied.

In his May 30, 2019, expert report, Dr. Cohen states, "Based on the relatively low levels to which she was exposed to C8 and her measured blood level of C8 and comparing her substantial increased risk of kidney cancer posed by her obesity and hypertension, it is my opinion that she would have developed kidney cancer even if she was not exposed to C8." (Cohen Report at 2).

Dr. Cohen confirmed during his deposition that this prohibited analysis was the foundation of all his opinions:

Q. Well, I'm talking about when you were weighing the relative risk factors of C8 versus the other ones, what were you -- what was it about C8 that made it less of a risk factor for you?

A. According to the scientific panel and these other publications, the average increased risk from C8 for kidney cancer is approximately 10 percent. Her exposure is below the average, so her increased risk would be anticipated to be less than that 10 percent, so that's what I went on.

(Deposition of Samuel Cohen, MD, June 14, 2019 at 36:5 to 36:16 ("Cohen Dep. Tr.") (Aff. Of Jon C. Conlin) (filed herewith) Exhibit. A).

Even when Dr. Cohen "assumes" Mrs. Swartz is a class member, he cannot help but quantify her exposure and use that as a basis to eliminate the causative risk of C8. "I have assumed that Mrs. Swartz's exposure to C8 was sufficient for her to qualify as a member of the Leach class, but her specific blood level (16.5 ng/ml) at the time it was measured (2006) was relatively low compared to the C8 blood levels of exposed individuals in the Ohio and West Virginia based on the evaluation by Barry et al. (2013) and Vieira et al. (2013)." (Expert Report of Samuel Cohen, MD, May 31, 2019 at 6 ("Cohen Report") (attached hereto as Exhibit B). This prohibited analysis was again confirmed during Dr. Cohen's deposition:

So is -- So in looking at Ms. Swartz particularly, did you factor in her -- the dose of her C8 level in discounting whether or not it was a substantial contributing cause to her cancer?

MR. MACE: Objection to form. You can answer.

A. I factored in her blood level that was taken I believe 2006, if I'm right, which placed

her at the low end of the C8 class of members for her overall blood level, which would put her below the mean for the overall risk.

(Cohen Dep. Tr. at 36:17 to 37:3).

As the Court explained in EMO 1, DMO 1, and DMO 1-A, "plaintiffs are not required to prove that their dose of and/or exposure to C-8 is capable of causing their Linked Diseases." Despite giving lip service to this Court's previous orders on general causation, it is clear that Dr. Cohen's opinions are entirely based on the forbidden foundation that Plaintiff's low class member tier puts her at less risk. Since this core analysis is strictly prohibited, all of Dr. Cohen's subsequent overlaying opinions are irrelevant. Because *Daubert* requires an expert's testimony be relevant in order to be admissible and because general causation is not an issue here, Dr. Cohen's opinions are irrelevant and should again be excluded just as they have each previous time he has attempted to give them.

**C. Dr. Cohen Failed to Conduct a Proper Differential Diagnosis.**

**1. Dr. Cohen did not rule in C8 as a cause of Plaintiff's cancer.**

As evidenced above, Dr. Cohen clearly does not believe that Plaintiff's exposure to C8 could have caused Plaintiff's cancer and he directly attacks the probable link general causation definition to come to that conclusion.

Throughout his report and deposition, Dr. Cohen repeatedly states that he assumed C8 was capable of causing kidney cancer in humans, including Mrs. Swartz, but clearly never considered it a significant risk factor. "[Mrs. Swartz] had two very significant risk factors for renal cell carcinoma, long standing obesity and hypertension." (Cohen Report at 6). This language makes it clear that Dr. Cohen is merely paying lip service to the Court's prior directives. Dr. Cohen simply stating that he considered C8 as "capable" of causing Plaintiff's cancer does not make it so when he never accepts or incorporates the Probable Link definition that it is "it is more likely than not

that [for Plaintiff] a connection exists between PFOA exposure and [kidney cancer]." (Probable Link Report at 2).

"Her amount of increased risk of developing kidney cancer from her C8 exposure would have been very small, and insignificant compared to her substantial amount of increased risk from her hypertension and her increased BMI." (Cohen report at 7). Dr. Cohen did not properly "rule in" C8 at the required weight of "more likely than not" as required by the Probable Link Finding.

**2. Assuming *arguendo* that Dr. Cohen "ruled in" C8, Dr. Cohen fails to explain a permissible methodology by which he "ruled out" C8.**

Even assuming *arguendo* that Dr. Cohen did "rule in" C8 as a potential cause of Plaintiff's cancer, Dr. Cohen fails to identify a valid methodology through which he was able to "rule out" C8 as "more likely than not" the cause of Plaintiff's cancer. This failure renders any results in a flawed and invalid differential diagnosis conclusion.

Dr. Cohen was required to include C8 as a possible risk factor for Plaintiff's cancer in doing his differential diagnosis. As stated by the Probable Link finding, C8 should have been considered "as more likely than not" for class members suffering from one of the linked diseases. However, as seen in both his report and deposition, Dr. Cohen "ruled out" C8 by impermissibly describing it as "low" or no more than 10%.

And so the basis of your opinion that she would have got -- that she would have gotten the renal cell carcinoma even without the exposure to C8 is because of her quoting you relatively low exposures to C8.

A. Correct.

Q. And when you say her relatively low exposures to C8, what are you referencing?

A. I'm referencing her blood level and where that fits into the overall distribution of blood levels of the C8 members.

(Cohen Dep. Tr. at 92:5 to 92:15).

This prohibited "low dose" argument then became the sole basis for all Dr. Cohen's comparative analysis of why obesity or hypertension must have instead been the cause of Plaintiff's cancer:

Q. So, again, your testimony is that her -- that her level of obesity and hypertension, as you perceive it from the records, is a greater risk of her getting kidney cancer than the C8 because of the dose level of C8 that she had.

A. The amount of -- Her risk from obesity and hypertension would be much greater than her risk from her exposure to C8 at that dose level.

(Cohen Dep. Tr. at 93:22 to 94:4).

Q. And your comparison of those, of those risk factors, is solely based -- of those other risk factors to C8 is solely based upon the low exposure dose level of her C8.

A. No, it's based on the overall assessment of the risk from those -- from obesity and hypertension itself compared to the C8 report and her distribution -- her place in the distribution of that blood level.

Q. So based upon her dose level.

MR. MACE: Objection to form.

A. As part of the overall evaluation. You have to put that in perspective with her obesity and hypertension.

Q. Fair enough. So what you're doing is you're looking at Ms. Swartz's dose level in comparative -- in comparison to where it falls against all the other dose levels within that class.

MR. MACE: Objection to form.

A. The distribution of the dose levels and also what the C8 points out with regard to the exposures in the general population and in the workers' population.

Q. Right. That's fine. But I'm saying that when you sit there and you say her dose level is too low, you're saying that –

MR. MACE: Objection.

Q. Well, when you say that her relatively low exposure to C8, quote, is that, it's based upon where her dose falls within the whole scope of the Leach class.

A. Correct.

I'm a bit confused on the question, but **let me explicitly state what I'm saying is that I think she's at the low end of the Leach class members, and so her overall risk would be at the low end of the C8 class; and compared to the risk that she has from hypertension and obesity, it would be very small.**

(Cohen Dep. Tr. 99:3 to 100:17) (emphasis added).

Q. Again, so her -- when you say her relatively low exposure to C8, you're talking about her blood serum level as it relates to the other individuals and the other class members.

A. Other individuals in the class, other –

Q. Right.

A. -- workers and the general population.

Q. Right. And so it was her blood serum level is -- was the basis for you saying that it was a relatively low exposure level to C8.

A. Yes.

Q. And that was the basis for you doing

15 your relative comparison to obesity and
16 hypertension and determining that those were
17 more probable for her diagnosis.

18 MR. MACE: Objection to form,
19 incomplete.

20 A. Yes.

(Cohen Dep. Tr. 110:3 to 110:20).

This weight and methodology analysis is clearly impermissible and erodes the language parties agreed to in the *Leach* Settlement agreement. As such, Dr. Cohen's opinions and testimony about both (1) C8 not being a substantial contributing cause and (2) obesity and hypertension being substantial contributing causes should be excluded just as they have each previous time he has tried to argue the same attack on general causation and the Probable Link Report findings. Because of Dr. Cohen's prohibited premises for all his opinions, his differential diagnosis is unreliable and should be excluded. (EMO 1-A at 6).

## IV. CONCLUSION

Dr. Cohen's opinions and testimony should be excluded because he proffers irrelevant general causation opinions and directly challenges the definition of the Probable Link Finding. Additionally, Dr. Cohen failed to conduct a proper differential diagnosis using the required Probable Link Finding definition before reaching his case-specific causation opinions that both (1) C8 was not a substantial contributing cause and (2) obesity and hypertension were substantial contributing causes. As such, because Dr. Cohen's purported specific causation opinions all fail to satisfy the requirements of *Daubert*, Federal Rule of Evidence 702, and this Court's prior holdings, these opinions are unreliable and inadmissible and should be excluded in full.

Respectfully submitted,

*/s/ Jon C. Conlin*

Jon C. Conlin
CORY WATSON, P.C.
2131 Magnolia Ave., Suite 200
Birmingham, AL 35205
Telephone: 205-328-2200
Fax: 205-324-7896
Email: c8@corywatson.com

Elizabeth E. Chambers
Nina M. Towle
Brett Thompson
CORY WATSON, P.C.
2131 Magnolia Ave., Suite 200
Birmingham, AL 35205
Telephone: 205-328-2200
Fax: 205-324-7896
Email: c8@corywatson.com

***Counsel for Plaintiffs***

**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the foregoing was electronically filed with this Court's CM/ECF on this 9th day of July, 2019 and was thus served electronically upon all counsel of record.

*/s/ Jon C. Conlin*